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Amendment  
Attorney Docket No. S63.2B-13170-US01

*Remarks*

This Amendment is in response to the Office Action dated July 18, 2006.

*Claim Rejections*

*35 U.S.C. §102(b)*

Vigil et al., U.S. 5320634

Claims 1, 2, 4-8, 10, 11, 13-16, 18, 20 and 21 have been rejected under 35 U.S.C. §102(b) as being anticipated by Vigil et al. (U.S. 5320634).

Applicants disagree.

Independent claims 1, 10 and 18 of the present application are directed to various embodiments in which an incising component (claims 1 and 18) or incising means (claim 10) and a pad (claims 1 and 18) or protective means (claim 10) are each positioned on a balloon wherein the pad is substantially parallel to and juxtaposed with the incising component.

The Office Action asserts that: Vigil et al. discloses an elongated, inflatable balloon having at least one incising component and a pad that is positioned on the balloon substantially parallel to and juxtaposed with said incising component (31, Fig. 2a) as recited in claim 1 of the present application.

Applicants submit that, in fact, Vigil et al. fail to disclose a pad which is juxtaposed with an incising component as recited in independent claim 1 of the present application. Vigil et al., see fig. 2A, disclose a balloon catheter with *seated* cutting edges wherein the atherotome is embedded in a substrate (see col. 4, lines 17-34). Even if the "substrate" of Vigil et al. can be found as being equivalent to a pad as recited in present claim 1, Applicants submit that "juxtaposed" is defined as being "side by side" and the atherotome

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embedded in the substrate as disclosed by Vigil et al. cannot be interpreted as being juxtaposed to one another.

Juxtaposed, as defined in The American Heritage College Dictionary, Houghton Mifflin Company, third edition, p. 738 (2000), is the following: "To place *side by side*, esp. for comparison or contrast." (emphasis added)

Applicants have made a minor amendment to independent claims 1, 10 and 18 to clarify that both the incising component and the pad are "on" the balloon, thus making it more clear as to the juxtaposition of the pad to the incising component. Applicants believe that this more accurately depicts the embodiments recited in claims 1, 10 and 18. See the figures in the present specification. No new matter has been added.

Applicants submit that Vigil et al. therefore does not anticipate independent claims 1, 10 and 18 of the present invention because Vigil et al. disclose embedding an atherotome in a substrate, and fail to disclose an incising component or incising means and a pad or protective means juxtaposed on a balloon surface as in claims 1, 10 and 18 of the present application. Claims 2 and 4-8 depend from claim 1 and are not anticipated by Vigil et al. for at least the reasons that claim 1 is not anticipated by Vigil et al. Claims 11, and 13-16 depend from claim 10 and are not anticipated by Vigil et al. for at least the reasons that claim 10 is not anticipated by Vigil et al. Claims 20 and 21 depend from claim 18 and are not anticipated by Vigil et al. for at least the reasons that claim 18 is not anticipated by Vigil et al.

Applicants respectfully request withdrawal of the rejection of claims 1, 2, 4-8, 10, 11, 13-16, 18, 20 and 21 under 35 U.S.C. §102(b) as being anticipated by Vigil et al. (U.S. 5320634).

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O'Brien, US 2005/0015107

Claims 1, 3, 4, 608, 12 and 19 have been rejected under 35 U.S.C. §102(e) as being anticipated by O'Brien (U.S. 2005/0015107).

The Office Action asserts that "[R]egarding claim 1 O'Brien discloses an elongated, inflatable balloon (14, fig. 2), at least one incising component (56, fig. 6,7), a pad having a outer surface (224, fig. 10), wherein said pad is positioned on said balloon (214, fig. 10) substantially parallel to and juxtaposed with said incising component (256, fig. 10)."

Applicants have amended independent claims 1, 10 and 18 to clarify that the pad is positioned on the balloon surface such that it is *spaced apart* from the incising component, as well as parallel to, and juxtaposed with the incising component. See at least FIG. 3B of the present specification for support thereof.

Applicants submit that the pad 224, Fig. 10, to which the Examiner refers in the Office Action, is actually a "....flexible member 224 that is *formed as a jacket* and bonded to the working portion of the balloon 214. As shown, the flexible member includes a cylindrically shaped wall 232 and four protuberances 236*a-d* that are formed as raised ridges with each ridge extending radially from the wall 232 of the flexible member 224 to a relatively sharp edge 256 that is aligned substantially parallel to the longitudinal axis 234....With this cooperation of structure, the wall 232 seamlessly interconnects the protuberances together." See paragraph 0031. In other words, the cylindrically shaped wall 232 and four protuberances 236*a-d* are all formed as a single unit which makes up the flexible member 224.

As discussed above, Applicants have amended independent claims 1, 10 and 18 to clarify that the pads and incising components are spaced apart from one another on the balloon surface.

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Thus, O'Brien, 2005/0015107, does not anticipate independent claims 1, 10 and 18 because O'Brien fails to disclose incising components and pads which are spaced apart from one another on the balloon surface.

Claims 3, 4 and 6-8 depend from claim 1 and are not anticipated by O'Brien for at least the reasons that claim 1 is not anticipated by O'Brien.

Claim 12 depends from claim 10 and is not anticipated by O'Brien for at least the reasons that claim 10 is not anticipated by O'Brien.

Claim 19 depends from claim 18 and is not anticipated by O'Brien for at least the reasons that claim 10 is not anticipated by O'Brien.

Based on the foregoing, Applicants respectfully request withdrawal of the rejection of claims 1, 3, 4, 608, 12 and 19 under 35 U.S.C. §102(e) as being anticipated by O'Brien (U.S. 2005/0015107).

***35 U.S.C. §103(a)***

Claims 9, 17 and 22 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Vigil et al. in view of Grayzel et al. (U.S. 6942680).

Independent claims 1, 10 and 18, from which claims 9, 17 and 22 respectively depend, have been amended and are patentable over Vigil et al. as discussed above.

Claims 9, 17 and 22 are directed to embodiments in which the incising component comprises a base and an elongated blade, wherein the base is mounted on the balloon and the blade mounted on the base, and the base is formed with a plurality of stiffeners.

It is asserted in the Office Action that "Grayzel teaches stiffening members on a balloon to increase stiffness and rigidity to reduce twists or kinks. Therefore, it would have been

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obvious to a person having ordinary skill in the art at the time the invention was made to modify Vigil et al. as taught by Grayzel to include stiffeners in the base.”

However, combining the stiffening members of Grayzel with Vigil et al., fails to render independent claims 1, 10 and 18 obvious because Vigil et al. fails to disclose or suggest incising component or incising means and a pad or protective means juxtaposed on a balloon surface as discussed above, and combining Grayzel with Vigil et al., still fails to suggest such a feature as recited in independent claims 1, 10 and 18.

Consequently, claims 9, 17 and 22 are not rendered obvious by Vigil et al. and Grayzel for at least the reasons that claims 1, 10 and 18 are not rendered obvious over this combination.

Applicants respectfully request withdrawal of the rejection of claims 9, 17 and 22 under 35 U.S.C. §103(a) as being unpatentable over Vigil et al. in view of Grayzel et al. (U.S. 6942680).

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**CONCLUSION**

Claims 1-22 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Claims 1, 10 and 18 have been amended as discussed above. No new matter has been added. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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